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UNITED STATES DISTRICT COURT  
DISTRICT OF NEW JERSEY

IN RE OUTLOOK THERAPEUTICS, INC.  
SECURITIES LITIGATION

THIS DOCUMENT RELATES TO:  
ALL ACTIONS

Case No. 2:23-cv-21862-MCA-CLW

CLASS ACTION

**DEFENDANTS' RESPONSE TO LEAD  
PLAINTIFFS' NOTICE OF  
SUPPLEMENTAL AUTHORITY**

Defendants submit this response to Plaintiffs’ Notice of Supplemental Authority, ECF No. 73, which attached the recent decision in *Levon v. CorMedix Inc. et al.*, No. 21-cv-14020 (JXN) (CLW) (D.N.J. June 30, 2025).<sup>1</sup> *CorMedix* is inapposite, and lends no credence to Plaintiffs’ efforts to avoid permanent dismissal of this action.

*First*, the allegations in *CorMedix* are worlds apart from the allegations in this case. In *CorMedix*, the plaintiffs alleged that the defendant drug company had performed an internal, “never disclosed” audit of its third-party manufacturer. *Levon v. CorMedix Inc. et al.*, No. 21-14020, 2025 WL 1810207, at \*1, 8 (D.N.J. June 30, 2025). The operative pleading supplied details from confidential witnesses (including the author of the audit report) about what the audit showed—namely, that the manufacturer was doomed to fail FDA inspections—and how its results were conveyed to management. *See id.* The court in *CorMedix* observed that these detailed allegations “directly contradicted” management defendants’ public statements throughout the class period that manufacturing issues had been “resolved” and their drug application was “on track.” *Id.* Here, there are no comparable, particularized allegations of information known to Outlook management that contradicted any public statements—instead, there is merely speculation. (*See* MTD SAC at 25-27.) Further, the plaintiffs in *CorMedix* alleged facts to show that the defendants had a motive to commit fraud; there are no such allegations here. *Compare CorMedix*, 2025 WL 1810207, at \*12 (motive “to facilitate two public offerings totaling \$60 million during the Class Period”) *with* MTD SAC at 2.

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<sup>1</sup> Unless otherwise noted, all capitalized terms are the same as those in Defendants’ Motion to Dismiss Plaintiffs’ Second Am. Compl., ECF No. 61 (“MTD SAC”) (ECF No. 61) and Reply in Support of Defendants’ Motion to Dismiss (ECF No. 72).

*Second*, the *CorMedix* decision contains pervasive and material inaccuracies; it mischaracterizes key authorities and includes quotations from case law and pleadings that cannot be found in the sources cited. This, at a minimum, severely curtails any persuasive value. While *CorMedix* purports to ground its analysis in exposition of other cases, those case discussions contain substantial errors. For instance, in finding scienter adequately pled, *CorMedix* relies heavily on *Dang v. Amarin Corp. PLC*, 750 F.Supp.3d 431 (D.N.J. 2024). According to *CorMedix*, the *Dang* “court applied the core operations doctrine where executives made misleading statements about Vascepa, the company’s only product, while ignoring FDA Form 483s and audits identifying significant regulatory risks,” and held that such facts “support scienter under both the core operations doctrine and the general PSLRA standard.” *CorMedix*, 2025 WL 1810207, at \*10 (citing *Dang*, 750 F.Supp.3d at 471-72). A cursory review shows that *Dang* supports none of this. “FDA Form 483s and audits” were not at issue in *Dang*; the drug company defendant had encountered issues related to patents. *Compare CorMedix*, 2025 WL 1810207, at \*10 *with Dang*, 750 F.Supp.3d at 449-51. *CorMedix* also gets the key holdings of *Dang* exactly backward; the *Dang* court **rejected** the plaintiffs’ reliance on the core operations doctrine and found that scienter **had not** been adequately pled. *See Dang*, 750 F.Supp.3d at 477 (noting that “the core operations doctrine does not permit imputing the requisite scienter regarding any statement made within a broad perimeter of the relevant core operations to an executive”). Further, *CorMedix* attributes a direct quotation to *Dang* (“classic evidence of scienter”) that does not appear in the case. 2025 WL 1810207, at \*8 (citing *Dang*, 750 F.Supp.3d at 464-65).<sup>2</sup> At bottom, *Dang* undermines, rather than supports, *CorMedix*.

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<sup>2</sup> *See also CorMedix*, 2025 WL 1810207, at \*7 (citing *City of Warwick Ret. Sys. v. Catalent, Inc.*, No. 23-1108, 2024 WL 3219616, at \*13 (D.N.J. June 28, 2024)). *CorMedix* attributes the following two quotations to *Catalent*: “The absence of insider trading is not dispositive,” and “The

Similarly, *CorMedix* states that the court in *In re Celgene Corp. Securities Litigation*, No. 18-4772, 2019 WL 6909463 (D.N.J. Dec. 19, 2019), “denied a motion to dismiss where defendants certified regulatory compliance despite undisclosed adverse FDA communications related to drug approvals.” *CorMedix*, 2025 WL 1810207, at \*10-11. But *Celgene* does not discuss certifications of regulatory compliance. And *CorMedix*’s citation to *Celgene* in this regard is a non sequitur, pointing to discussion of the element of loss causation rather than scienter. *See CorMedix*, 2025 WL 1810207, at \*10-11 (discussing the element of scienter while repeatedly citing *Celgene*, 2019 WL 6909463 at \*22, which addresses the element of loss causation).

Finally, the *CorMedix* opinion attributes statements to the defendants which they are not alleged to have made. According to the opinion, one individual defendant “publicly stated that CorMedix ... had ‘resolved all issues related to manufacturing,’” and CorMedix publicly stated “in October 2019 ... that the company had ‘all necessary controls and processes in place for approval.’” *CorMedix*, 2025 WL 1810207, at \*7 (citing Third Am. Consolidated Class Action Compl., ¶¶ 6, 7, *Levon v. CorMedix Inc.*, No. 21-cv-14020 (D.N.J. Apr. 22, 2024), ECF No. 97 (“*CorMedix* TAC”).). Neither statement appears in the *CorMedix* TAC. The *CorMedix* court’s apparent misapprehension of defendants’ statements casts significant doubt on its conclusions. *See Stoneridge Inv. Partners, LLC v. Scientific-Atlanta, Inc.*, 552 U.S. 148, 157 (2008) (first element of Section 10(b) claim is “a material misrepresentation or omission by the defendant”).

Plaintiffs’ counsel in this action is also counsel for the plaintiffs in *CorMedix*. That Plaintiffs’ counsel chose to ask this Court to rely on the *CorMedix* opinion without reservation, while staying silent as to its issues, is troubling.

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importance of the product to the company’s financial success supports the inference of scienter.” Neither sentence appears in the *Catalent* opinion.

Ultimately, *CorMedix* is of no moment here. Defendants respectfully reiterate their request that the Second Amended Complaint be dismissed with prejudice.

Dated: July 15, 2025

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**CERTIFICATE OF SERVICE**

I, Caroline Pignatelli, hereby certify that on July 15, 2025, I authorized the electronic filing of the foregoing with the Clerk of the Court using the CM/ECF system which will send notification of such filing to the registered participants as identified on the Notice of Electronic Filing.

/s/ Caroline Pignatelli

Caroline Pignatelli